## GRONEK & ARMSTRONG

ATTORNEYS AT LAW

98TH FLOOR - SEARS TOWER' 233 SOUTH WACKER DRIVE CHICAGO, ILLINOIS 60606

TEL: (312) 655-1800 FAX: (312) 655-1808

DENNIS M. GRONEK ROBERT E. ARMSTRONG PAUL J. WISNIEWSKI DEBORAH L. RUSS JACQUELINE P. KULER

July 10, 2003

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Point Branch Pkwy College Park, MD 20740



Re:

Notification for Statements on Dietary Supplement Labels

Dear Sir/Madam:

This firm represents Soteria Corporation, Jenison, Michigan, a distributor of dietary supplement products (hereinafter "Soteria"). Soteria has requested that we notify your Agency on its behalf of the inclusion of statements of nutritional support on its dietary supplement product labels.

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. §343(r)(6), and in accordance with the authorized provisions of 21 CFR §101.93(a), your Agency is hereby notified that Soteria has made a statement of "nutritional support", as described in 21 U.S.C. §343(r)(6)(A), for its dietary supplement as follows:

## Product Name

## Label Statement

SOcoral

Supports the skeletal system.

The undersigned hereby certifies on behalf of Soteria that the information contained in this correspondence is complete and accurate.

Sincerely yours,

**GRONEK & ARMSTRONG** 

Paul J. Wisniewski

CC: Soteria Corporation

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